

# Intranasal TXA for anterior epistaxis in the emergency department

Protocol ID: 19-001

4.30.19

## Protocol and Design

This is a prospective study to evaluate the efficacy of TXA on anterior epistaxis in the ED.

Inclusion criteria: Patients 18 years and older with anterior epistaxis.

Exclusion criteria: Patients with inability to give consent, patients without a working telephone number, patients lacking the mental capacity to make their own decisions, patients with posterior epistaxis, epistaxis following major trauma, patients with known bleeding disorder like hemophilia and thrombocytopenia, prisoners, patients hemodynamically unstable, pregnant patients, patients with a known allergy to TXA, and patients with a visibly bleeding vessel. Those recently post-op nasal/sinus surgery (within ten days) will also be excluded.

Additional information obtained including patient's past medical history and documentation of which, if any, anticoagulants they are taking.

### Interventions:

For the intervention stage of the study:

Informed consent will be obtained prior to patient enrollment.

Enrolled patients will be placed in one of two groups: either the group receiving a cotton pledget soaked in (0.9%) saline or (100mg/1mL) TXA. Patients will initially be asked to gently blow their nose to remove any clots. Group 1 will receive the saline soaked pledget. After fifteen minutes the pledget will be removed. If patient continues to bleed within a reevaluation period of fifteen minutes, this will be deemed a 'failure' and the examiner will pack the nose with the method of his or her choice. Group 2 will receive the TXA soaked pledget and the procedure will continue like Group 1.

### PROCEDURE TO FOLLOW:

Pledget soaked in either saline or TXA will be applied to the bleeding nare of the patient presenting with anterior epistaxis. After fifteen minutes, the pledget will be removed and patient reassessed.

The following occurs after a patient has been screened for inclusion and exclusion criteria (Participant Selection):

Informed consent form is explained to patient. If patient chooses to participate in the study, the patient signs informed consent and equipment will be obtained. (Patient Consent)

Order placed for TXA vs saline pledget and ENT cart in ED. (Prescribing)

\* Administration instructions will be entered by examiner after obtaining folder with patient's group number- examiner will place order for saline or TXA, nosebleed tray kit containing cotton pledgets and ENT cart in EPIC. Nurse will obtain materials and bring to bedside.

Nurse will confirm with examiner which group patient is in -either saline or TXA. (Verification)

Nurse and examiner will prepare pledget with either saline or TXA and have it ready at bedside.  
(Administration)

Expected enrollment: 86 patients

E. Data Collection: A folder will be prepared and kept at Boardman Hospital (at charge nurse desk) and St Elizabeth Youngstown Hospital (in physician break room) with 86 total forms (43 at each hospital). Each form will contain either Group 1 or Group 2, which will be arranged in alternating order. The examiner will know which group the patient is in, but the patient is blinded as to whether he or she will be receiving a TXA or saline soaked pledget. After pledget placed by examiner and patient reassessed in fifteen minutes, examiner will document whether bleeding ceased or whether further intervention was needed. Patient satisfaction will be assessed at time he or she receives discharge instructions and patient will be contacted via telephone after 7 days and asked whether bleeding recurred and patient satisfaction will again be assessed. At this point, form will be placed in the section of completed forms for examiner to collect once the 86 patients have all gone through the study. If a patient comes back to the ED with a nosebleed after being a participant in the study, he or she will not be re-enrolled.

#### Statistical Analysis Plan

All data in this study will be considered non-parametric and will be analyzed using non-parametric statistical analyses. Primary outcome will be compared using chi-square test (nominal dependent/non-parametric). A sample size calculation was performed yielding a total of 86 patients (43 per group) to achieve 80% statistical treatment failure as primary outcome. Secondary outcome of bleeding cessation as well as patient satisfaction will be assessed using chi-squared testing. All statistical analysis presumed a significant alpha level as  $< 0.05$ .